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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,143	03/26/2001	Michael G. Walker	PB-0004-1 CIP	2083

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EXAMINER

CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/24/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/818,143

Applicant(s)

WALKER ET AL.

Examiner

Karen Cochrane Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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At pages 27 and 28, the specification teaches that the polynucleotides co-expressed with known matrix remodeling proteins are correlated with at least 2 known matrix remodeling proteins by having a correlation p-value of less than 10^{-7} , or $-\log$ of 8 and above. Below is depicted an abbreviated table much like that shown in Table 4 at page 27, with the highest correlated known matrix proteins (KMP) and their functions set forth. If there were multiple KMPs having the same correlated score, these are listed as well.

<u>SEQ</u>	<u>Clone</u>	<u>KMP</u>	<u>Function</u>
1	606132	MMP	matrix metalloproteinases including collagenases
2	627722	hevin	extracellular matrix protein (NOTE that there are no scores greater than 7)
3	639644	CTGF	connective tissue growth factor
4	1362659	coll 1; VI	collagen 1 and VI
5	1446685	col IV	collagen IV
6	1556751	C/DSPG	chondroitin/dermatan sulfate proteoglycans
7	1656953	MGP	matrix Gla protein; regulates calcification of cartilage
8	1662318	col IV	collagen IV
9	1996726	coll III	collagen III
10	2137155	BM-40	osteonectin; induces MMP synthesis
11	2268890	fibrillin	extracellular microfibrils
12	2305981	fibulin; MGP	binds fibrinectin, platelet adhesion, cleaved by MMP; regulates calcification of cartilage
13	2457612	CTGF; MGP	connective tissue growth factor; regulates calcification of cartilage
14	2814981	col IV; VII; MMP	collagen IV; VII; matrix metalloproteinases
15	3089150	C/DSPG	chondroitin/dermatan sulfate proteoglycans
16	3206667	MGP	Matrix Gla protein, regulates calcification of cartilage
17	3284695	MGP	Matrix Gla protein, regulates calcification of cartilage
18	3481610	hevin; MGP	extracellular matrix protein; regulates calcification of cartilage
19	3722004	TIMP-1; 3	tissue inhibitor of MMP
20	3948614	col IV	collagen IV

Note that the sequences depicted as SEQ ID NO: 1-20 co-express with nucleic acid encoding known matrix proteins having different functions. SEQ ID NO: 1-20 differ in structure as well. Therefore, this restriction requirement will separate the nucleic acids having SEQ ID NO: 1-20 because these DNAs vary in structure and are co-expressed with DNAs encoding proteins having different functions. The function of the polypeptides encoded by SEQ ID NO: 1-20 is not provided, though SEQ ID NO: 2, 6, and 11 encode SEQ ID NO: 21, 22, and 23, having paralemin,

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opsin, and angiopoitin activity, respectively (page 29), based on sequence homology, which activity does not correlate with the activity of the known matrix protein co-expressed with SEQ ID NO: 2, 6, or 11.

Note that broad method claims will be searched even when a specific ligand is elected – see below. The election of the ligand provides a starting point for the search. However, if art is found against the broad claim, the search will stop at the elected ligand.

Note that methods of using an elected nucleic acid or polypeptide can be rejoined in accordance to *In re Ochiaie*.

Note that the claims were not numbered sequentially, in that Claim 7 is missing. Thus, the claims have been renumbered in accordance to Rule 126.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 1, classified in 536/23.1.
2. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 2, classified in 536/23.1
3. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 3, classified in 536/23.1
4. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 4, classified in 536/23.1
5. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 5, classified in 536/23.1.
6. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 6, classified in 536/23.1.
7. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 7, classified in 536/23.1.
8. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 8, classified in 536/23.1
9. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 9, classified in 536/23.1
10. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 10, classified in 536/23.1
11. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 11, classified in 536/23.1.
12. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 12, classified in 536/23.1

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13. Claims 1-3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 13, classified in 536/23.1
14. Claims 2, 3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 14, classified in 536/23.1.
15. Claims 2, 3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 15, classified in 536/23.1.
16. Claims 2, 3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 16, classified in 536/23.1.
17. Claims 2, 3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 17, classified in 536/23.1.
18. Claims 2, 3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 18, classified in 536/23.1.
19. Claims 2, 3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 19, classified 536/23.1.
20. Claims 2, 3, 12, 13, and 14, drawn to polynucleotides having SEQ ID NO: 20, classified 536/23.1.
21. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 1, classified in 435/6.
22. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 2, classified in 435/6.
23. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 3, classified in 435/6
24. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 4, classified in 435/6
25. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 5, classified in 435/6.
26. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 6, classified in 435/6.
27. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 7, classified in 435/6.
28. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 8, classified in 435/6
29. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 9, classified in 435/6.
30. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 10, classified in 435/6.
31. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 11, classified in 435/6.
32. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 12, classified in 435/6.
33. Claims 4-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 13, classified in 435/6.
34. Claims 6-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 14, classified in 435/6.
35. Claims 6-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 15, classified in 435/6.
36. Claims 6-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 16, classified in 435/6..

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- 37. Claims 6-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 17, classified in 435/6..
- 38. Claims 6-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 18, classified in 435/6..
- 39. Claims 6-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 19, classified in 435/6.
- 40. Claims 6-8, drawn to method for identifying ligands to polynucleotides having SEQ ID NO: 20, classified in 435/6.

If any one of Inventions 21-40 is elected, Applicant are requested to also elect a molecule selected from DNA, RNA, peptide nucleic acids, mimetics, and proteins as set forth in Claims 5 and 8. These molecules differ in structure and function and therefore are considered to be patentably distinct.

- 41. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 1, classified in 435/6.
- 42. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 2, classified in 435/6.
- 43. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 3, classified in 435/6.
- 44. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 4, classified in 435/6.
- 45. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 5, classified in 435/6.
- 46. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 6, classified in 435/6.
- 47. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 7, classified in 435/6.
- 48. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 8, classified in 435/6.
- 49. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 9, classified in 435/6.
- 50. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 10, classified in 435/6.
- 51. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 11, classified in 435/6.
- 52. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 12, classified in 435/6.
- 53. Claims 9-11, drawn to method for detecting gene expression of polynucleotides having SEQ ID NO: 13, classified in 435/6.

- 54. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 1, classified in 530/350.
- 55. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 2, classified in 530/350.
- 56. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 3, classified in 530/350.
- 57. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 4, classified in 530/350.

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58. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 5, classified in 530/350.
59. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 6, classified in 530/350.
60. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 7, classified in 530/350.
61. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 8, classified in 530/350.
62. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 9, classified in 530/350.
63. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 10, classified in 530/350.
64. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 11, classified in 530/350.
65. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 12, classified in 530/350.
66. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 13, classified in 530/350.
67. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 14, classified in 530/350.
68. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 15, classified in 530/350.
69. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 16, classified in 530/350.
70. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 17, classified in 530/350.
71. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 18, classified in 530/350.
72. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 19, classified in 530/350.
73. Claims 15 and 16, drawn to protein encoded by polynucleotides having SEQ ID NO: 20, classified in 530/350.

74. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 1, classified in 435/7.1.
75. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 2, classified in 435/7.1.
76. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 3, classified in 435/7.1.
77. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 4, classified in 435/7.1.
78. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 5, classified in 435/7.1.
79. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 6, classified in 435/7.1.
80. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 7, classified in 435/7.1.
81. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 8, classified in 435/7.1.

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82. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 9, classified in 435/7.1.
83. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 10, classified in 435/7.1.
84. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 11, classified in 435/7.1.
85. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 12, classified in 435/7.1.
86. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 13, classified in 435/7.1.
87. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 14, classified in 435/7.1.
88. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 15, classified in 435/7.1.
89. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 16, classified in 435/7.1.
90. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 17, classified in 435/7.1.
91. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 18, classified in 435/7.1.
92. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 19, classified in 435/7.1.
93. Claims 17-19, drawn to method of using polypeptide encoded by polynucleotides having SEQ ID NO: 20, classified in 435/7.1.

If any one of Inventions 74-93 is elected, Applicant are requested to also elect a molecule selected from DNA, RNA, peptide nucleic acids, mimetics, and proteins as set forth in Claim 18. These molecules differ in structure and function and therefore are considered to be patentably distinct.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Inventions 1-20 are related to the protein of Inventions 54-73, respectively, by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

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Inventions 1-20 and Inventions 21-40 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the recombinant production of protein.

Inventions 1-13 and Inventions 41-53, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the recombinant production of protein.

Inventions 54-73 and Inventions 74-93, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the production of antibody.

The nucleic acids of Inventions 1-20 are not used in the methods of Inventions 74-93 and therefore Inventions 1-20 and 74-93 are patentably distinct.

The proteins of Inventions 53-74 are not used in the methods of Inventions 21-53 and therefore Inventions 53-74 are patentably distinct.

The methods of Inventions 21-53 and 74-93 require different products and different steps and therefore Inventions 21-53 and 74-93 are patentably distinct.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

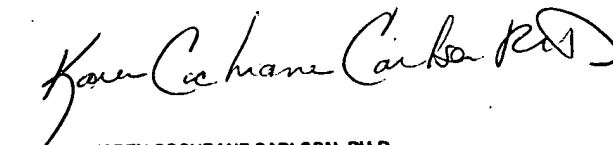
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

June 20, 2003


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER